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August 25, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher's Lane  
Room 1061  
Rockville, MD 20852

**Re: FDA Docket No 97D-0138: Guidance for Industry Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products [Federal Register: August 17, 1999 (Volume 64, Number 158)]**

To Whom it May Concern

The American Association of Blood Banks (AABB), America's Blood Centers (ABC) and the American Red Cross (ARC) wish to take the opportunity to comment on this guidance. The AABB, ABC, and ARC jointly represent all of the blood collecting organizations and over 80% of the blood transfusion services in the United States.

We are commenting jointly to request deletion of the question "Since 1980, have you knowingly obtained and been injected with a non U.S. licensed drug product made from cattle, such as bovine (beef) insulin?" These comments also make recommendations for modifying the language of other questions, both for risk of exposure to BSE and for identifying donors at increased risk for CJD. There may be additional aspects of the Guidance that will require comment at a later date, but comments on this particular issue are being filed immediately because of the need to resolve these issues rapidly.

- **Request for deletion of question "Since 1980, have you knowingly obtained and been injected with a non U.S. licensed drug product made from cattle, such as bovine (beef) insulin?"**

The question for identifying donors who may have been exposed to bovine-derived injectable products made in BSE endemic countries will not be effective. Answers to this question will be meaningless, if not inaccurate. This information is so obscure that the vast majority of donors will have absolutely no way of answering this question with any degree of accuracy. We also question whether blood centers and/or donors will know or even be able to determine the species and locale from which an injectable product was derived, and whether it was from a US licensed facility. Blood centers do not have the resources to be able to research products that may be mentioned. The meaning of the term "knowingly" is also extremely vague. Finally such a question will distract donors from careful consideration of more important questions.

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It is inappropriate to add this type of question without public discussion and industry comment for both the rationale and impact. This subject matter has not been discussed at the Transmissible Spongiform Encephalopathy Advisory Committee Meeting or at the Blood Product Advisory Committee Meeting and therefore, there has been no previous opportunity to make our concerns known.

- **Request for modification of language**

**We request that the requirement to specifically list each of the six UK countries be removed.**

The proposed language for Question 1 “Have you visited in or lived in the UK(England, Northern Ireland, Scotland, Wales, the Isle of Man, or the Channel Islands) from 1980 through 1996?” makes the question very long, both to print and to read. There are other methods for providing that information such as posted signs, or through provision of that information in the educational material which is given to donors prior to the screening interview.




**We request that the AABB Uniform Donor History Questionnaire be permitted to continue to use the current terminology which was previously approved by FDA: “Have you received a dura mater (brain covering) graft?”**

The language as proposed by the Guidance has as a lead in question “Have you ever had brain surgery?” This question is much broader and will increase the time necessary to screen donors, and require additional documentation on the part of the donor interviewer when the initial answer is yes. This question also does not include an inquiry about spinal surgeries in which dura mater is sometimes used. We do not suggest that the question should include asking about spinal surgery for the same reason we do not ask about brain surgery. Asking a more direct question about dura mater will elicit the necessary information without adding confusion about other types of brain and/or spinal surgery.

- **We agree with the language of the other questions, and particularly appreciate the change to human pituitary derived hormones such as growth hormone or gonadotropin. We have also had this addition under consideration.**

Although there is a six month implementation date, the agency should be aware that many places are planning implementation much more rapidly. It is essential that the issues relating to donor questions are resolved and communicated expeditiously before many blood centers have implemented the guidance as written.

If you have any questions or wish to communicate directly with us, please contact Kay Gregory, at 301-215-6522 or [kayg@aabb.org](mailto:kayg@aabb.org).

		
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